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14. ABSTRACT This BAA is providing core program support to develop key capabilities of the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program to lead medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during the past year, progress was made on interoperability-related standards, including gap analyses; a multi-institutional/industry working group defined safety components of a prototype regulatory submission of an integrated medical device system and handed off its work products to the FDA; an updated version of the MD FIRE contracting language is being reviewed by the VA and other federal agencies; our mobile PCA safety demonstration was reconfigured with smaller, more adaptable components; notable progress was made in collaborations with the VA, NIST, and other federal agencies, leading to joint projects and initiatives.					
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**Annual Report: Medical Device Plug-and-Play Interoperability
Standards and Technology Leadership
Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2010 – 20 September 2011**

[Note: The initial BAA award period was amended to end September 20, 2011, and the first option-year was exercised to run through September 20, 2012. This report is an Annual Report covering the period of 21 September 2010 through 20 September 2011.]

Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device “Plug-and-Play” (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments, and we developed a strategy to accelerate the development of interoperability technologies as well as standards. The strategy addressed the need for a “sandbox” laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a “plug-and-play” system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors’ legal concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify and access numerous available resources, and to build collaborations to achieve MD PnP objectives. TATRC’s commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and most recently NIH. We have created a medical device interoperability lab at CIMIT in Cambridge, MA, as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety and exhibited these at national meetings. We held an international conference on “Improving Patient Safety through Medical Device Interoperability and High Confidence Software”, jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead and achieve the writing and submission of the first medical device integration system standard – the Integrated Clinical Environment (ICE) standard, Part I, which includes functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices. In addition, we led a successful collaborative effort of three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement by seven medical societies (including the American Medical Association) of medical device interoperability for improving patient safety. We worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing “program glue” to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

We planned and co-sponsored with the FDA and Continua Health Alliance a three-day workshop on Medical Device Interoperability in January 2010, attended by over 200 participants from industry, health care, and federal agencies. There has been a follow-on working group

meeting regularly to address safety and regulatory concerns for integrated medical device systems.

Body of Report

The MD PnP Program has become a recognized leader in medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This requires critical evaluation (or “gap analysis”) of potentially suitable candidate standards, as well as the modification of existing standards and development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development, so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the U.S. FDA to define interoperability-related hazards and their mitigations to help inform a regulatory pathway for networked medical device systems, as well as developing the MD PnP Lab as a “sandbox” populated with medical devices and test equipment to serve as a vendor-neutral environment to perform interoperability testing and conformance testing to evaluate proposed standards. Building on what has been accomplished to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards development
- Open clinical platform development
- Clinical and engineering requirements for MD PnP
- Regulatory pathway
- Inclusion of device interoperability in the national health IT agenda

Since the program’s inception, more than 800 clinical and engineering experts, and representatives of more than 100 companies and institutions have participated in four plenary workshops / conferences, working group meetings, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, Draper Laboratory, FDA, NIST, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Kansas State, New Hampshire, Waterloo (Canada), and Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, DocBox Inc., Moberg Research Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, NSF/CPS (Cyber Physical Systems), Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare Information Systems).

For the period of this grant, we proposed the following objectives:

Standards Development

- Address remaining formal comments on the ICE standard (ASTM F-2761), Part I, resulting from balloting within ASTM, and see it through to publication.
- Convene the working and writing groups for the next part of the ICE series of standards (probably the “network controller” and “device models”); manage their work to produce preliminary draft standards.

- Complete the gap analysis of the capability of the IEEE 11073 medical communication series of standards to support the use cases outlined in Part I of the ICE standard in partnership with DoD- and NSF-funded collaborators.
- Participate in standards activities synergistic with ICE, e.g. IEEE 11073 and IEC 80001 (risk management of medical devices connected to IT systems).
- Incorporate results of ICE platform development (see below) to improve the ICE series of standards.

Open Clinical Platform Development

- Leverage the CIMIT-funded development of a prototype clinical platform for improving PCA safety to assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of an open ICE development platform.
- Develop architecture for the clinical prototype platform to conform to the ICE standard.
- Identify requirements for the broader open ICE platform to support iterative clinical applications.

Clinical and Engineering Requirements for MD PnP

- Refine the existing database of clinical scenarios and categorize in terms of ICE elements and safety-critical factors, to enhance its utility as a use case repository for use by the interoperability development community.
- Identify the most important medical devices to include in interoperability development efforts.
- Apply our use case / clinical requirements analysis methodology to the ICE use cases.

Regulatory Pathway

- Continue collaborating with the FDA on standards, on gap analysis, and on identifying a regulatory pathway for ICE-compliant medical devices.
- Work with the FDA to plan a workshop on medical device interoperability for December 2009 or Q1 2010.

Program Development and Management

- Continue to build collaborations with patient safety and technical organizations.
- Provide oversight and coordination to the various collaborative groups working on projects related to the ICE platform (ICE Platform Integration Coordination working group: ICE-PIC).
- Continue to work with healthcare delivery organizations to further develop the MD FIRE contracting language and to utilize it in appropriate RFPs and contracts.
- Enable the PI to play a coordinating role for the various TATRC-funded SBIR projects aimed at furthering medical device interoperability (MD PnP “glue”).
- Leverage the NSF-funded work to support TATRC goals, and vice versa, to enhance federally-funded outcomes.
- Investigate Center or Program Grants that could support development and utilization of the MD PnP program and lab as a national resource for medical device interoperability.

Research Accomplishments

Standards Development

Objective 1: Address remaining formal comments on the ICE standard (ASTM F-2761), Part I, resulting from balloting within ASTM, and see it through to publication.

A multi-institutional writing group, led by Dr. Goldman and convened by ASTM International Committee F29 – including engineers and standards experts from Partners HealthCare System, the FDA, Draper Lab, Draeger Medical, MITRE Corporation, Philips Medical, DocBox Inc., and

University of Pennsylvania – produced the preliminary draft of Part I of the multi-part ICE standard (“Integrated Clinical Environment”) that embodies the elements of the overall technology ecosystem to safely implement networked medical device systems. This draft was submitted by ASTM F29 as a New Work Item Proposal (NWIP) to the IEC/ISO international standards development organizations in late 2007. It received a tie vote in ISO, which was insufficient for adoption as a New Work Item. Many comments were submitted – supportive comments from healthcare delivery systems and criticism from companies with proprietary interests.

The ASTM ICE writing group systematically reviewed and addressed all 161 submitted comments on Part I, a lengthy effort but one that contributed to an improved standard: Part I was re-scoped and re-named “General requirements and conceptual model,” and outlines the more specific ICE parts still to be written. During the period of this grant, ICE Part I was successfully balloted within ASTM and additional comments were addressed. ICE Part I, “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE),” was published by ASTM as F2761-2009 in December 2009. The ICE standard started being used immediately by international standards bodies and consortia, small companies with DoD SBIR and STTR support, and universities that are doing related research.

The medical device interoperability standards landscape has been stirred up by the FDA over the past year. Many standards organizations (including ASTM) want to be involved in the further development of ICE and other related standards. The FDA has specifically asked AAMI (Association for the Advancement of Medical Instrumentation) to pursue the development of interoperability standards, and AAMI’s ad hoc working group on HITI has just produced a draft report (to which we contributed) on the state of interoperability standards (see **Objective 4**). The FDA held a one-day meeting in July to bring together representatives of various standards development organizations (SDOs) to discuss how to progress the completion of device interoperability standards.

Objective 2: Convene the working and writing groups for the next part of the ICE series of standards (probably the “network controller” and “device models”); manage their work to produce preliminary draft standards.

Because the effort to systematically address the ICE Part I comments required substantial rewriting of the draft standard within officially convened standards meetings, the launch of work on subsequent parts had to be postponed. The ICE conceptual model that evolved made it clear that development of Parts II and III (device and system models, and the network controller) would need to proceed in parallel, due to the interdependencies of the proposed requirements and functionality. We convened a multi-institutional ASTM writing group in September 2009, including several new participants from small businesses that had received DoD SBIR Phase I awards for ICE-related development. Initial drafting of Parts II and III was begun. This meeting clarified that the development of device models requires broader collaboration and expertise.

Follow-on work from the January 2010 FDA Workshop on Medical Device Interoperability (see **Objectives 12 & 13**) has produced valuable information about device models and the network controller that will inform development of the standard. During the past year, work on our NIH project has further elucidated the complex requirements of device and system models, and the network controller. With this important work ongoing, we have achieved timely results through less formal working groups that are learning from real-world experience. It has become clear that it was necessary to complete this level of detailed requirements work before reconvening the ICE writing group. We plan to do that within the next six months.

Our MD PnP team has been directly involved with both the FDA and AAMI in standards efforts and will continue to work with all parties to see that existing standards are improved and new ones developed where needed. That will need to constitute the fulfillment of the intent of **Objective 2**. In the meantime, essential preparatory work for the standards is underway and can be applied regardless of the SDO. We still intend to draft requirements and architecture material from our NIH Quantum work and from the FDA Prototype Regulatory Submission Working Group and submit that in the appropriate SDO venues to inform development of ICE and related standards.

Objective 3: Complete the gap analysis of the capability of the IEEE 11073 medical communication series of standards to support the use cases outlined in Part I of the ICE standard in partnership with DoD- and NSF-funded collaborators.

The ICE-PAC – a team of MD PnP collaborators that includes leaders of medical device communication standards groups, medical device manufacturers (such as Philips, GE, and Draeger), small system integrators, and recently NIST – has been performing detailed workflow analysis of the clinical scenarios that were incorporated into the ICE Part I standard, and has been analyzing the ability of the IEEE 11073 set of standards to meet these requirements. The group has completed most of the functions in ICE use cases, and their work has fed the NIH project and other MD PnP-related activities, as well as enabling collaborative work with other organizations, notably the IHE (Integrating the Healthcare Enterprise). The NIST team led by Vince Stanford, Project Manager & Systems Architect, Information Technology Laboratory at NIST, with which we are collaborating, is also involved with this project.

Objective 4: Participate in standards activities synergistic with ICE, e.g. IEEE 11073 and IEC 80001 (risk management of medical devices connected to IT systems).

Several of our MD PnP team members attended the AAMI annual meeting in June 2011 and participated in standards-related discussions. The AAMI Ad-Hoc Group on Health Information Technology and Interoperability (AAMI/HITI) was formed early in 2010 to explore how AAMI could expand its work beyond its traditional role of medical device safety to explore important areas in HIT and interoperability. We have worked closely with this group, and we helped draft the July report that the AAMI/HITI group prepared for the AAMI Standards Board regarding AAMI's role in medical device interoperability standards. We subsequently learned that, although labeled a draft, this report was passed along to the Standards group at FDA.

In June Dr. Goldman chaired the annual ISO TC121 standards meeting. At that meeting, he held a special session on “Advanced Clinical Requirements”, and vetted clinical and safety requirements with a subgroup of experts at the June 2011 Anesthesia Patient Safety Foundation (APSF) workshop, which included over 100 participants from industry and clinical organizations. In August we hosted a meeting of the ISO/IEC JWG7 on 80001, focused on alarm standards. The ongoing participation of Dr. Goldman and other MD PnP team members in these standards activities is critical because devices under the purview of different companies will have to conform to common interoperability specifications, including ASTM ICE.

We have also been participating in related standards groups, particularly the AAMI Infusion Device and Assurance Case Draft Guidance groups, and we are working with AAMI to develop a Quality System standard to support the FDA February 2011 MDDS Final Rule. We are also working with UL to plan an ICE-interface certification standard. These standards and regulatory activities shape the environment in which ICE is used, and we have been able to use the ASTM ICE standard to help.

Objective 5: Incorporate results of ICE platform development to improve the ICE series of standards.

When we reconvene the ICE writing group, learnings from our ICE platform development work will be incorporated in the standard.

Open Clinical Platform Development

Objective 6: Leverage the CIMIT-funded development of a prototype clinical platform for improving PCA safety to assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of an open ICE development platform.

Over the past year we have worked on a detailed re-engineering of our PCA safety demonstration, which is enabling us to progress on our platform development as well as multiple internal projects. Most of our future platform work will be done under the NIH grant, and we expect to be able to leverage that for TATRC goals.

We have continued working with members of the Open Biomedical Ontologies group to understand the range of nomenclatures and how they can be used in ICE device models and the Network Controller and Data Logger. The International Conference on Biomedical Ontologies Adverse Event Analysis Workshop, where we presented our work in July, was a fruitful opportunity to engage with the Biomedical Ontologies community. We have also been working on clarifying requirements around device identification, especially the role of the FDA Unique Device Identifier regulation and how it will influence our planned device identification mechanisms. Dr. Goldman chaired a panel at the FDA UDI meeting in September.

In the spring a group of Boston University undergraduate biomedical engineering students completed their senior design project on the X-Ray / Ventilator Use Case. We worked closely with the students to help them understand the scenario and device interface requirements, and they completed a hazard analysis of the individual devices and the complete system, which we are using in our ongoing research. Their project was also presented as a poster at the September 2011 IEEE EMBS conference.

Objective 7: Develop architecture for the clinical prototype platform to conform to the ICE standard.

We are continuing to use the BeagleBoard as an inexpensive, open source development platform. We are currently working on adding a network time protocol (NTP) client and server to the system, in order to provide a trusted master time reference.

We have been working with a team of engineers at Intel Corporation to identify and model clinical scenarios, including the PCA safety use case, in a variety of simulated hospital IT networks. This work will help to clarify functional requirements for the ICE Network Controller and ICE External Interface, as well as safety requirements for the PCA scenario, such as the maximum number of pumps that can be managed reliably by a control application in an integrated clinical environment. The project will also help Intel with requirements for their processor roadmap, which will support adoption of device interoperability.

Objective 8: Identify requirements for the broader open ICE platform to support iterative clinical applications.

Our team has been working on device interface requirements and device models, including a draft specification for a general ICE device model, as well as requirements for the ICE Network

Controller. We wrote an initial overview of some of the safety and privacy issues and requirements for ICE, which was presented at and published in the proceedings of the IEEE EMBS conference in September 2011.

One critical component of an ICE platform is the data logger, which addresses safety, liability, and regulatory needs. Although limited in function for our initial PCA prototype, this implementation is elucidating some of the issues that will need to be addressed in Parts II and III of the ICE standard, as well as in a broader open ICE platform. Development of a working prototype, including capabilities required to “play back” data from the data logger to re-create clinical events, is a larger effort, and we have submitted a separate proposal to TATRC for this.

We have also begun collecting data on the issue related to device clock time errors and erroneous data time-stamps in preparation for a White House-led meeting on this topic. A poster on data collected at MGH was shown at our September 7th Open House.

Clinical and Engineering Requirements for MD PnP

Objective 9: Refine the existing database of clinical scenarios and categorize in terms of ICE elements and safety-critical factors, to enhance its utility as a use case repository for use by the interoperability development community.

The activity of identifying and refining high-level clinical scenarios, in order to lay the foundation for developing technical specifications for medical device interoperability, is ongoing. The clinical use cases we have collected are being used as highly-valued input for work by our industry and university collaborators, and several archetypal use cases representing different aspects of interoperability were included in Annex B of the ICE standard, Part I.

Collaborative work with DocBox Inc. and with our NIH collaborators, under other funding, is contributing to the refinement of project-specific clinical requirements and use cases. This effort is yielding detailed workflow and requirements from an engineering perspective, and is expected to feed back additional details into the workflow documentation. For example, students from Boston University hired by DocBox for the summer developed further requirements for the x-ray / ventilator synchronization use case, and their results were presented in a poster at the MGH Scientific Advisory Committee’s poster day in April.

A very basic prototype of a web-deployable secure requirements database to facilitate collection of clinical scenarios and respective clinical and equipment requirements was developed by summer interns a year ago. Objectives for the Option-Year we have just begun include completing requirements for this use case repository, and obtaining feedback from FDA, NIST, and AAMI. We will also be working on a plan for managing a web-based interface to facilitate broader collection of new use cases and refinement of existing ones, while protecting the integrity of the database. Our recent proposal to TATRC covers plans to build, test, and deploy the use case repository.

Objective 10: Identify the most important medical devices to include in interoperability development efforts.

This objective is completed, and a list of Key Medical Devices for Interoperability Scenarios is included as Attachment A to this report. We have also completed an initial template for identifying device-specific data that is important to support interoperability – the Medical Device Interface Data Sheet – and we have included a sample data sheet for a device on the mobile cart as Attachment B.

Objective 11: Apply our use case / clinical requirements analysis methodology to the ICE use cases.

This objective is completed, as we have utilized our analysis methodology throughout the process of working on clinical scenarios and use cases.

Regulatory Pathway

Objective 12: Continue collaborating with the FDA on standards, on gap analysis, and on identifying a regulatory pathway for ICE-compliant medical devices.

An engineer from the FDA's Center for Devices & Radiological Health (CDRH) has been a regular participant in the team that has been developing the ICE standard, and has participated with the Prototype Regulatory Submission working group and its successor, the Medical Device Interoperability Safety working group. He is a senior advisor for our program and is frequently consulted.

Led by Dr. Goldman, the Prototype Regulatory Submission working group (20 participants from industry, clinical care, standards development organizations, and regulatory agencies) continued to meet via weekly teleconferences throughout the past year to develop a detailed risk / regulatory model for an integrated "prototype" regulatory submission. A face-to-face meeting at the FDA was held in November 2010. The output of the group was turned over to FDA at their request in May 2011. The group has continued to meet subsequently as the Medical Device Interoperability Safety working group.

Objective 13: Work with the FDA to plan a workshop on medical device interoperability for December 2009 or Q1 2010.

Jointly sponsored by the FDA, CIMIT and the Continua Health Alliance, the FDA Workshop on Medical Device Interoperability was held in January 2010 at the FDA and was attended by more than 150 technical, clinical, and regulatory experts in person, including medical device manufacturers, IT and communications vendors, healthcare providers, researchers, consultants, and government experts from the FDA, NIH, VA, NSF, and NIST. Another 50-60 participated in the live web-cast of the workshop. The program consisted of plenary speakers to define the issues and set the context, use case presentations and discussions by a range of stakeholders, and breakout sessions to allow groups with similar interests to target important issues and to delve deeper into the problems and possible solutions.

This workshop was the strongest action the FDA has taken to show its commitment to medical device interoperability. Slides and streaming video of the workshop presentations are available at our MD PnP web site: http://mdpnp.org/FDA_Interop_Workshop.php. These pages have received over 5000 visits thus far.

Program Development and Management

Objective 14: Continue to build collaborations with patient safety and technical organizations.

Our successful approach to convening and facilitating diverse MD PnP stakeholders has been a key part of the program, as evidenced by our increasing collaborations with groups interested in achieving medical device interoperability.

We engaged with Lockheed Martin Corporation (LMC) on a collaborative project (currently internally funded by Lockheed) to use simulation in virtual clinical environments to facilitate investigation of safety aspects of medical device interoperability and the proposed ICE platform. The first prototype, based on ICU alarm scenarios provided by our program, was deployed in

the MD PnP Lab in August, and was shown to a cross-institutional group of CIMIT consortium members in late September, generating great interest. LMC plans to build on our pilot project and further develop the virtual world for healthcare applications.

Over the past several months we have engaged with Intel in a collaborative project to simulate network loads of device throughput. This will help develop building blocks for the ICE platform.

Our ties with the Office of the National Coordinator for Health IT (ONC) were greatly strengthened during the past year. Our NIH/NIBIB grant was adopted by ONC as an affiliate of the ONC-funded SHARP (Strategic Health IT Advanced Research Projects) program (http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_sharp_program/1806). ONC has worked hard to help promote our interoperability efforts, for example by including us on the SHARP program web page and in their standard SHARP slide deck. In February we participated in the ONC booth and in SHARP-related activities at HIMSS11 (where we also participated in the TATRC booth in the Military Health Systems area). In July 2011 we participated in the SHARPFest meeting in Washington, which provided a great opportunity to present our work to the other grantees and look for potential collaboration. There are plans being developed currently for a “pan-SHARP” project that involves us with their four grantees.

In March 2011 Dr. Goldman gave invited testimony at a Public Hearing on “Identification of Barriers and Enablers for Device Interoperability”, for the HIT Standards Committee, Clinical Operations Workgroup, in Washington DC.

We worked with Vince Stanford at NIST during the past year on a collaborative project using NIST’s internal Data Flow System to implement ICE use cases as a proof of concept of medical device interoperability. This work is also expected to yield a gap analysis of 11073 standards relative to ICE use cases.

Existing relationships with the VA have led to collaboration on several fronts. In October 2010 Dr. Goldman gave the keynote address at a cross-VA meeting focused on medical device interoperability. The group formed the VA Medical Device Interoperability Program (MDIP) Stakeholder Council, intended to coordinate interoperability efforts across the VA, with Dr. Goldman as its mentor and external advisor. The group has been meeting monthly by telecon to work on specific goals to further interoperability. One of these goals is to review the MD FIRE contracting language and make recommendations for VA adoption. Dr. Goldman presented information to the VA MDIP Council in June on how hospitals can interpret and respond to the FDA’s ruling on Medical Device Data Systems (MDDS).

Objective 15: Provide oversight and coordination to the various collaborative groups working on projects related to the ICE platform (ICE Platform Integration Coordination working group: ICE-PIC).

Although no specific new projects were generated by ICE-PIC, individual collaborative groups are working on their own ICE-related projects, and our program has remained a touchstone for sharing learnings and ideas from this work.

Objective 16: Continue to work with healthcare delivery organizations to further develop the MD FIRE contracting language and to utilize it in appropriate RFPs and contracts.

During the past year we have continued to work with various organizations on an updated version of the MD FIRE contracting language, and there has recently been increased focus by three groups. The Medical Device Interoperability Program group at the VA (formed in October 2010 with Dr. Goldman as a mentor) has set a goal of producing a version of MD FIRE by

December 2011 to propose for VA adoption. TATRC has recently re-engaged in an effort to integrate MD FIRE in the DoD procurement process. The Indian Health Service has asked to join the process of refining the MD FIRE language. All of these groups will be important participants in developing a strategy for broader adoption.

Objective 17: Enable the PI to play a coordinating role for the various TATRC-funded SBIR projects aimed at furthering medical device interoperability (MD PnP “glue”).

This objective no longer applies in the absence of SBIR projects, but Dr. Goldman remains available to provide advice as requested for other TATRC-funded efforts aimed at furthering medical device interoperability. Also, we have ongoing discussions and collaboration with both Moberg Research and DocBox Inc., which are funded by TATRC. Dr. Goldman continues to identify and highlight synergies he observes between and among relevant TATRC-funded activities.

Objective 18: Leverage the NSF-funded work to support TATRC goals, and vice versa, to enhance federally-funded outcomes.

Dr. Goldman continues to participate in meetings of the NSF Computer & Information Science & Engineering (CISE) Advisory Committee. He has supported TATRC’s participation in interagency meetings where medical device interoperability was discussed in terms of a government agency collaborative effort. Since receiving our 5-year NIH grant in October 2010, which also led to adoption of our NIH project by the ONC SHARP program, we have been able to leverage that work to support TATRC medical device interoperability goals as well. We continue our ongoing investigation of other appropriate pathways for support of this work through NIH, NSF, ONC, NIST, and the VA.

Objective 19: Investigate Center or Program Grants that could support development and utilization of the MD PnP program and lab as a national resource for medical device interoperability.

The concept of the MD PnP “sandbox” Lab has been a key component of the MD PnP vision, and making the Lab operational in 2006 provided a physical anchoring point for the program and enabled the implementation of use case demonstrations to illustrate the concepts and feasibility of MD PnP. Partners HealthCare Information Systems engineers provided a “virtual medical network” infrastructure to support multiple devices and a test environment. The Lab’s potential was demonstrated during the June 2007 HCMDSS / MD PnP Workshop, when nine interoperability-related demos were brought in by industry and academic institutions. Current activities were demonstrated at an open house in September 2011, where our Quantum collaborators joined us in showing interoperability-related demonstrations.

Our 5-year NIH Quantum grant is enabling us to build up our lab resources (people, devices, and software tools). We believe we will be well positioned by the end of the Quantum project to apply for a center grant.

In the meantime, we expect to make significant use of our lab in collaborative projects with the University of Pennsylvania (NSF), VA Boston and Boston University (CIMIT), the National Institute of Standards & Technology (NIST), and a joint effort with Partners HealthCare, the VA, and the New England Health Information Network for sharing veterans health data between EHRs.

Key Research Accomplishments

- **ASTM “ICE” standard.** A multi-institutional writing group led by the MD PnP program and convened by ASTM International – including engineers and standards experts from industry, healthcare systems, government and academia – produced Part I of the multi-part ICE standard (“Integrated Clinical Environment”) that embodies a systems engineering framework to safely implement integrated multi-vendor medical device systems. These building blocks will enable flexible development and deployment of decision support and advanced monitoring systems. Part I was published as ASTM F2761-2009 and development of subsequent parts is underway. Work on the ICE standard has guided and informed other related standards work, e.g. the IHE PCD domain, gap analysis of the ability of the IEEE 11073 set of standards to support the clinical use cases described in ICE, and the 2010 HITSP Technical Note 905 (http://bit.ly/HITSP_TN905).
- **Interoperability contracting language.** The MD PnP program led a collaborative project of Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine to jointly author an interoperability procurement guide. In October 2008 we published this document as a “call to action” to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This collaboration has produced sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise, http://bit.ly/MD_FIRE_Page). An updated version of MD FIRE will be published shortly, and further work is currently being done by the VA and other agencies.
- **Medical society endorsements/end-user “pull”.** From March 2007 to June 2009, through MD PnP program leadership, the need for medical device interoperability was endorsed by seven medical societies – the American Medical Association, Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and the Massachusetts Medical Society. These endorsements continue to be a powerful motivator for other groups considering deeper engagement. Example text:

Intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. We also recognize that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.
- **Collaborative R&D.** The Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) and MD PnP Interoperability, funded by TATRC and NSF and held in June 2007, led to extensive collaborations with the University of Pennsylvania and the University of Illinois at Urbana-Champaign. The Cyber Physical Systems program at NSF funded each of them for three-year projects (now extended to four years: 2008-2012) to work with our program to investigate safety-critical aspects of networked medical device systems, and awarded a five-year grant in 2010 to University of Pennsylvania that is synergistic with MD PnP efforts. Our work with DoD/TATRC

SBIRs and with other collaborators has informed research priorities for NSF and other agencies.

- **CIMIT MD PnP Lab.** The CIMIT MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by our university collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management). In 2010 Lockheed Martin Corporation installed a prototype of a co-developed virtual clinical world simulation tool. We have ongoing work in the Lab on our Quantum project and projects with NIST and CIMIT investigators, and we intend to host additional inter-institutional projects there.
- **Regulatory pathway.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Over the past six years we have studied and elaborated the issues and solutions surfaced by medical device interoperability stakeholders. An important step towards FDA buy-in was the three-day workshop on medical device interoperability planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA in January 2010. This workshop brought together over 200 participants from stakeholder communities to explore the issues and roadmap potential solutions (<http://bit.ly/5Kj5X9>). As follow-up to the workshop, a working group comprised of companies, standards organizations, clinical and legal participants, and the FDA has met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. This group handed off its work products to the FDA in Spring 2011, for further internal development at FDA, and has continued to meet under Dr. Goldman's leadership as the Medical Device Interoperability Safety working group.
- **Relationships with federal agencies.** In addition to the FDA, the MD PnP program has been working with NIST, NSF, the Office of the National Coordinator for Health IT, and the VA Office of Joint Interoperability Ventures. Recognition of the critical role of device interoperability in the national health IT agenda has increased greatly over the past year, as evidenced by the ONC interest in adopting our Quantum grant as part of the SHARP program, as well as interest expressed by Aneesh Chopra, the Federal CTO, in hosting a workshop to address device clock time synchronization issues.
- **Non-DoD Funding.** In October 2010 we received a 5-year grant from NIH/NIBIB, a significant vote of confidence in our work and achievements to date. This Phase II grant was built on the foundation of TATRC-supported research – a Phase I equivalent. We also received a grant from NIST, and a subcontract from the University of Pennsylvania as part of its 5-year grant from NSF Cyber Physical Systems.

In addition to the specific achievements above, the MD PnP program has in the past year gained increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are

helping to further the aims of the program. CIMIT continues to provide space for the MD PnP Lab and for ten program offices.

Reportable Outcomes

45+ Meetings:

- September 2010 – May 2011 – weekly teleconference calls of the Prototype Regulatory Submission (PRS) working group
- May 2011 – September 2011 – weekly teleconference calls of the Medical Device Interoperability Safety working group (successor to the PRS)
- September 21 2010 – CIMIT ICE delegates meeting focused on medical device interoperability and ICE STORM demos
- September 28-29 2010 – 2nd Annual Medical Device Connectivity Conference, San Diego, CA
- October 1 2010 – kick-off meeting for CIMIT project with VA Boston and DocBox
- October 6 2010 – CIMIT Executive Briefing for Lockheed Martin Corporation, to discuss potential collaboration
- October 7 2010 – VA meeting on Medical Device Standards and Interoperability, which led to forming a cross-VA Council
- October 18 2010 – meeting with national VA Biomedical Engineering group, San Diego, CA
- November 1 2010 – kick-off meeting for NIH Quantum project, Cambridge, MA
- November 16 2010 – Prototype Regulatory Submission (PRS) working group meeting at FDA
- November 16 2010 – SHARP Collaborative Meeting at AMIA Annual Symposium, Washington DC
- December 13 2010 – kick-off meeting at University of Pennsylvania for NSF Medical Device Cyber Physical Systems 5-year grant, Philadelphia, PA
- December 14 2010 – ANSI / ASTM F29 standards meeting, New York, NY
- December 15 2010 – meeting at NIH/NIBIB with program officers and NIBIB leadership
- January 3 2011 – visit to MD PnP Lab by Dr. Soojin Park from University of Pennsylvania
- January 10 2011 – clinical scripting meeting and Quantum architecture meeting at FDA, Silver Spring, MD
- January 14 2011 – MD PnP session on awareness under anesthesia use case at Society for Technology in Anesthesia annual meeting, Las Vegas, NV
- January 20 2011 – kick-off meeting of VA Medical Device Interoperability Program (MDIP) Stakeholder Council, Cambridge, MA (Dr. Goldman is mentoring this group)
- February 3 2011 – presentation by NIST to MD PnP program team on collaborative work, Cambridge, MA
- February 11 2011 – visit to University of Massachusetts Medical Center to discuss collaboration, Worcester, MA
- February 14 2011 – meeting with VA to discuss MDIP Stakeholder Council Objective on Medical Device Consistent Time (telecon)
- February 2011 – Sept 2011 – monthly meetings of VA MDIP Stakeholder Council (telecons)
- February 21 2011 – meeting at HIMSS of SHARP grantees with EHR Association, Orlando, FL

- February 22 2011 – meeting at HIMSS with hospital delivery systems to discuss MD FIRE and FDA ruling on Medical Device Data Systems, Orlando, FL
- March 15 2011 – TATRC Product Line Review, Washington, DC
- March 16 2011 – meeting with Doug Fridsma on Standards, ONC, Washington, DC
- March 23-24 2011 – AAMI/FDA standards meeting Reston, VA
- April 4 2011 – NIBIB Quantum Principal Investigators meeting, Bethesda, MD
- April 7 2011 – telephone meeting with Free Software Foundation to discuss approaches to sharing open source software
- April 13 2011 – ExactData webinar for MD PnP Quantum team
- May 7 2011 – meeting of NSF Computer & Information Science & Engineering (CISE) Advisory Committee, Washington DC
- May 11 2011 – ASTM F29 standards meeting, Philadelphia, PA
- May 20 2011 – meeting with GE Healthcare's Academic Research Programs Manager to discuss potential collaboration, Cambridge, MA
- May 26 2011 – telephone meeting of AAMI HIT ad hoc group
- June 8 2011 – Anesthesia Patient Safety Foundation Summit on PCA issues, Phoenix, AZ
- June 12-17 2011 – ISO TC 121 standards meeting, Vancouver, BC
- July 11-12 2011 – SHARPFest meeting of SHARP project teams, Washington, DC
- July 27 2011 – White House HIT SSG meeting, Washington, DC
- August 16 2011 – invitation-only interagency workshop on "The Role and Future of Health Information Technology in an Era of Health" sponsored by White House Office of Science & Technology Policy, Washington, DC
- August 25-27 2011 – 80001 alarm standards meeting, Cambridge, MA
- September 6 2011 – Quantum Year 2 strategic planning and outcomes meeting, Cambridge, MA
- September 7 2011 – MD PnP Lab open house (demos by our program and collaborators), Cambridge, MA
- September 8-9 2011 – 3rd Annual Medical Device Connectivity Conference, Boston, MA
- September 12-13 2011 – FDA meeting on Unique Device Identification, Silver Spring, MD
- September 19-20 2011 – MD PnP program strategic planning meetings, Cambridge, MA

19 Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

- September 21 2010 at CIMIT ICE delegates meeting, Cambridge, MA
- September 28 & 29 2010 keynote address and regulatory panel at Second Annual Medical Device Connectivity Conference & Exhibition, San Diego, CA
- October 7 2010 at Veterans Affairs meeting on Medical Device Standards and Interoperability, Boston, MA
- October 9 2010 at 3rd Annual Critical Care Bioinformatics Workshop, Case Western Reserve University, Cleveland, OH
- October 18 2010 at Veterans Health Administration Biomedical Engineers national meeting, San Diego, CA
- November 2 2010 on MD FIRE at Beth Israel Deaconess Medical Center, Boston, MA

- November 9 2010 at the U.S. Critical Illness & Injury Trials (USCIIT) Group, Bethesda, MD
- December 15 2010 seminar for NIBIB leadership and program officers at NIH, Bethesda, MD
- January 20 2011 at kick-off meeting of VA Medical Device Interoperability Program (MDIP) Stakeholder Council (webinar)
- February 21 2011 at HIMSS / ONC SHARP session on Vendor Engagement with Federal IT Research Efforts, Orlando, FL
- March 15 2011 at TATRC Product Line Review, Washington, DC
- April 4 2011 at NIBIB Quantum grant PIs meeting at NIH, Bethesda, MD
- April 30 2011 at workshop on Integrated Clinical Environments: The Future of Improved Healthcare, Singapore
- June 1 2011 at the Veterans Health Administration Real Time Location Systems Conference, Atlanta, GA
- June 30 2011 to VA “Medical Device Interoperability Program” (MDIP) Stakeholder Council
- July 11 2011 at SHARPFest meeting of SHARP project teams, Washington, DC
- September 8 2011 keynote address at Third Annual Medical Device Connectivity Conference, Boston, MA

Dave Arney delivered presentations on medical device interoperability topics to the following groups during the past year:

- April 11 2011 at the MD PnP / High Confidence Medical Device Software & Systems workshop at the NSF Cyber Physical Systems conference, Chicago, IL
- July 29 2011 at Adverse Event Analysis Workshop at the International Conference on Biomedical Ontology, Buffalo, NY

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program – provides access to ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop – receives 400-500 visits per week

Manuscripts/Publications:

- Arney D, Weininger S, Reed TL, Whitehead SF, Goldman JM, “Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System,” Publication in: *Proceedings of International Conference on Biomedical Ontology*, July 2011.

Funding Applications Facilitated by this BAA to Date (total costs shown):

- Funded: CIMIT: for FY10 program leader support
- Funded: CIMIT: for FY11 program leader support
- Funded: CIMIT: for FY11 support for development of a pre-clinical PCA closed-loop control application
- Funded: CIMIT: for FY11 support for interoperability of portable x-ray devices with ventilators in an ICU at a VA hospital (collaboration with VA Boston)
- Funded: CIMIT: for FY11 support for development of a clinical algorithm-driven interoperable smart ventilator (collaboration with Boston University)

- Funded: CIMIT: for FY12 support for prototype demonstration of veterans health data exchange between 3 EHR systems (collaboration with VA HITIDE, TATRC, and NwHIN)
- Funded: TATRC: for MD PnP subcontract on Moberg Research SBIR Phase II award
- Funded: TATRC: for MD PnP subcontract on DocBox Inc. award
- Funded: NIST: for evaluation of ICE functional requirements for medical device interoperability (standards gap analysis)
- Funded: NSF: for MGH subcontract on University of Pennsylvania 5-year award for assuring safety, security, and reliability of medical device systems
- Funded: NIH/NIBIB: for 5-year development of prototype healthcare intranet, an open ICE platform
- Not Funded: Office of Naval Research: for 5-year development of prototype acute critical care system of integrated medical devices for safer, monitored transport of wounded warriors from battlefield to care facility

Other: In-kind engineering support and/or contribution of equipment for the lab from Draeger Medical, Philips Healthcare, FDA, Draper Laboratory, Kaiser Permanente, University of Pennsylvania, LiveData Inc., and DocBox Inc.

Lockheed Martin joined CIMIT's Industry Liaison Program in order to work with CIMIT and the MD PnP program, and provided of equipment to run and display their virtual clinical environments prototype.

Conclusions

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to provide important clinically focused leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies and the White House; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in the past year in attracting funding from several federal agencies (NIH, NSF, NIST), as well as CIMIT, all of this funding is project-specific and does not support the standards work, convening, and program infrastructure that the TATRC funding has so greatly enhanced.

Notable achievements enabled or facilitated by this TATRC support include:

- We led the development of an international standard for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International;
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership, and a second iteration of this language is now being reviewed by the VA and Indian Health Service;

- Seven medical societies (including the AMA) have endorsed the need for medical device interoperability;
- Strong collaborations have been established with the Veterans Administration and with federal agencies, including the Office of the National Coordinator for Health IT and the White House, putting medical device interoperability on the national healthcare agenda;
- The FDA held a jointly sponsored Workshop on Medical Device Interoperability, worked with an MD PnP/industry working group on defining components of a prototype regulatory submission of a system of integrated medical devices, and is now reviewing the output of that working group.

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the “program glue” to effectively leverage these synergies to realize our mutual program objectives.

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Appendices

Draft of Key Medical Devices for Interoperability Scenarios
Participants in Medical Device Interoperability Safety Working Group
Medical Device Interface Data Sheet – Generic
Device Clock Synchronization Study Poster
X-Ray / Ventilator Synchronization Use Case Poster

Appendix A

Draft of Key Medical Devices for Interoperability Scenarios

The following list of devices are key for the four clinical scenarios we are developing for the Quantum project, and they are commonly used in acute care settings, so will be relevant for many of the interoperability scenarios we will work with across multiple projects. In addition, we have identified some key home care devices and key systems that will be involved in acute care scenarios.

Acute Care Devices

Infusion Pumps

- PCA
- Large-Volume
- Syringe

Ventilator

Anesthesia Machine

Pulse Oximeter

Integrated Patient Monitor

ICU Bed

Capnograph

Depth of Sedation Monitor

EKG machine

Home Health Devices

Glucometer

Pulse Oximeter

Insulin Pump

Hospital and Network Systems

Nurse Call System

Hospital EMR

NHIN (National Health Information Network)

Appendix B

Medical Device Interoperability Safety Working Group (MDISWG) MD PnP Program

AdvaMed
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Anakena Solutions
Ed Ramos
Mike Robkin

Anson Group
Russ Gray
Scott Thiel

Capsule Technologie
Peter Kelley

DEKA Research
Kevin Durand
Roger Leroux

DocBox, Inc.
Jere McLucas
Tracy Rausch
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Medical Device Interface Data Sheet

Generic Example

June 2011

The attached spreadsheet contains an example Medical Device Interface Data Sheet (MDIDS). We are developing a set of these data sheets to describe the required interface capabilities of devices used in selected Clinical Scenarios.

The attached “generic” MDIDS contains common device functions and related data elements that will be found in most of the device-specific MDIDS forms we are developing. These elements include device identification data such as Serial Number, FDA-mandated Universal Device ID (UDI) where available, software version numbers, and a description of the data encoding used for device-specific data elements. Other categories of data found in the generic MDIDS are Patient Identification and Location information, as well as data about the Operating Conditions of the device and its Configuration.

We have developed initial MDIDS forms for the Pulse Oximeter, Anesthesia Workstation, Defibrillator, and Dialysis Machine. Each of these forms contains device-specific information in addition to the generic data. For instance, the Anesthesia Workstation describes an additional 19 Measurement Variables and 113 Alarms that the Workstation can produce.

As we develop the MDIDS library, we will continue to add variables, alarms, and other data to the forms. These data items will come both from existing devices on the market, as we survey their capabilities, and from an analysis of the future device capabilities necessary to support Clinical Scenarios.

The MDIDS, once complete, will provide the standards, MDM, research, regulatory, and healthcare organization community with a compendium of device interface requirements that can be used for product and standards development and device procurement.

Generic MDIDS

			As an Output				As an Input				
Variable	Symbol	Currently Available for Integration	Required	Desired	Not Important	Not Sure	Required	Desired	Not Important	Not Sure	Required
Device Identification											
Serial Number											
UID											
Model Number											
SW Rev 1											
SW Rev 2 (if exists)											
SW Rev 3 (if exists)											
Firmware Rev											
Encoding/Ontology (e.g. IEEE 11073)											
Certificates of Interoperability Conformance											
Certificates of Security											
Manufacturer											

Patient Identification											
Last Name											
First Name											
Hospital-issued Patient ID											
Other ID											
Height											
Weight											
Sex											
Birthdate											
BSA											

Location Information											
Hospital Name/Site Number											
Unit											
Room											
Bed											

Generic MDIDS

			As an Output				As an Input				
Variable	Symbol	Currently Available for Integration	Required	Desired	Not Important	Not Sure	Required	Desired	Not Important	Not Sure	Required

Operating Variables											
Humidity											
Temperature											
Clock Time											
Battery Level											
Self Test Results											

Device Configuration											
Network Address											
Mode/Library in Use/etc.											

Contact Information											
Name											
Title											
Company											
Email											
Phone											

Generic MDIDS

Waveform as output							
Variable	Desired	Not Important	Not Sure	Unit(s) of Measure (check all that apply)	Units Used for Transmission (check all that apply)	Are there alarm limits associated to this variable?	If 'yes', should the alarm limits be adjustable remotely?
Device Identification							
Serial Number							
UID							
Model Number							
SW Rev 1							
SW Rev 2 (if exists)							
SW Rev 3 (if exists)							
Firmware Rev							
Encoding/Ontology (e.g. IEEE 11073)							
Certificates of Interoperability Conformance							
Certificates of Security							
Manufacturer							

Patient Identification							
Last Name							
First Name							
Hospital-issued Patient ID							
Other ID							
Height							
Weight							
Sex							
Birthdate							
BSA							

Location Information							
Hospital Name/Site Number							
Unit							
Room							
Bed							

Generic MDIDS

		Waveform as output					
Variable	Desired	Not Important	Not Sure	Unit(s) of Measure (check all that apply)	Units Used for Transmission (check all that apply)	Are there alarm limits associated to this variable?	If 'yes', should the alarm limits be adjustable remotely?
Operating Variables							
Humidity							
Temperature							
Clock Time							
Battery Level							
Self Test Results							

Device Configuration							
Network Address							
Mode/Library in Use/etc.							

Contact Information							
Name							
Title							
Company							
Email							
Phone							

Generic MDIDS

Variable	If 'yes', should the alarm priority be adjustable remotely?	If 'yes', should the alarm be suspended or dismissed remotely?	Should the Date/Time of adjustments be logged?	Desired Average Window/Frequency (examples: for a parameter: 10 seconds; for an alarm, event or display setting: upon Admit or when changed)
Device Identification				
Serial Number				
UID				
Model Number				
SW Rev 1				
SW Rev 2 (if exists)				
SW Rev 3 (if exists)				
Firmware Rev				
Encoding/Ontology (e.g. IEEE 11073)				
Certificates of Interoperability Conformance				
Certificates of Security				
Manufacturer				

Patient Identification				
Last Name				
First Name				
Hospital-issued Patient ID				
Other ID				
Height				
Weight				
Sex				
Birthdate				
BSA				

Location Information				
Hospital Name/Site Number				
Unit				
Room				
Bed				

Generic MDIDS

Variable	If 'yes', should the alarm priority be adjustable remotely?	If 'yes', should the alarm be suspended or dismissed remotely?	Should the Date/Time of adjustments be logged?	Desired Average Window/Frequency (examples: for a parameter: 10 seconds; for an alarm, event or display setting: upon Admit or when changed)
Operating Variables				
Humidity				
Temperature				
Clock Time				
Battery Level				
Self Test Results				

Device Configuration				
Network Address				
Mode/Library in Use/etc.				

Contact Information				
Name				
Title				
Company				
Email				
Phone				

Generic MDIDS

Variable	Should there be a remote message when calibration/maintenance is required?	Direct or Calculated Measure	Desired Reference Standard (if applicable)
Device Identification			
Serial Number			
UID			
Model Number			
SW Rev 1			
SW Rev 2 (if exists)			
SW Rev 3 (if exists)			
Firmware Rev			
Encoding/Ontology (e.g. IEEE 11073)			
Certificates of Interoperability Conformance			
Certificates of Security			
Manufacturer			

Patient Identification			
Last Name			
First Name			
Hospital-issued Patient ID			
Other ID			
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Mode/Library in Use/etc.			

Contact Information			
Name			
Title			
Company			
Email			
Phone			

Asynchronous Medical Device Clocks in the Hospital

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MD PnPTM
Getting connected for patient safety

Introduction

Clinical measurements and events are timed-stamped in the Electronic Medical Record (EMR). The time of measurements is important for patient care, research, and has medico-legal implications. EMR time stamping is configurable. The EMR may use the time stamp that the medical device assigns to the data, or may assign a time stamp when the data is acquired.

Despite the importance of accurate time stamps, many medical devices do not set their clock using a network time reference. In fact, these clocks are usually set manually twice a year. Also, there is no adopted standard for medical device time management, and no method to maintain consistency among all time stamps contained in the patient's EMR.

In a typical operating room, there is a wide array of different clocks in use: a clinician's watch or mobile device, a clock on the wall, a patient's monitor, anesthesia machine, or an infusion pump. Most medical device clocks are not networkable and maintain their own date and time stamps. These device clocks are manually set when the devices are put in use, usually using a personal watch or mobile device for reference. When documenting a clinical event, any of these clocks may be cited. Furthermore, the same clock is not consistently used when documenting events which can make back-tracking through the patient's events error prone.

To understand the severity of the situation, medical device clocks from the operating rooms, intensive care units, and storage facilities at Massachusetts General Hospital were recorded. These clocks were compared to the National Institute of Standards and Technology (NIST)'s Internet Time Service to compare clock consistency and evaluate deviance between device clocks within the hospital.

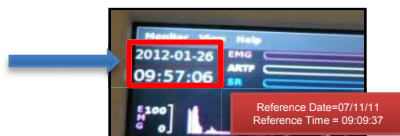


Figure 1 - Incorrect date & time on a Brain Function Monitor

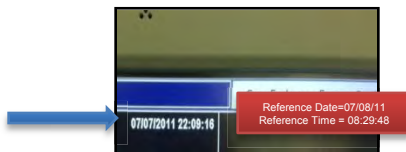


Figure 2 - Incorrect date & time on an Imaging System

Method

Time Stamp acquisition protocol:

The following protocol describes how the difference between the time displayed on a device and the time of a reference clock was obtained and calculated. A digital camera with an internal clock was used to take all photos during the study. This gave an offset from the device clock to the camera clock. By also taking a photo of a reference clock, for instance an NTP-synchronized computer clock, the offset between the camera clock and the reference clock could be calculated. The sum of these two offsets gave the difference between the device clock and the reference clock.

Determining the offset:

A photo was taken of a reference clock from NIST: <http://nist.time.gov/> including hours, minutes, and seconds. Then, another photo was taken of the clock, including seconds, from the computer that was used to analyze the data. Consequently, the time shown in the photos could be manually compared to the clock time recorded by the camera in the photo's EXIF data (photo data file) to determine all device clock offsets with respect to NIST.

Device Clock Acquisition:

Photos of device clocks were taken. Many devices had a clock display on their main display panel. Some devices required access to a special configuration page to view the clock time. The location and type of each device (e.g., OR 7, ICU room 12) was documented. Locations and types were documented in two ways: with a paper list (e.g., photos 2 – 17 are from OR 7); or by taking a photo of the room's number sign before entering to photograph the device clocks.

HIPAA Regulation:

Patient identity and PHI was carefully avoided when taking the photo of the device's clock. This required covering patient names, room numbers, etc. on the display before taking the photo or carefully framing the photo to omit the name. Photos were examined to ensure that PHI would not be included in the database.

Calculating the Offset:

The location and types of each device and the displayed clock time and EXIF time from each photo was input in a spreadsheet. Also input was the time from the reference clock and the EXIF time from the reference photos. The time offset for each device was calculated.

Results

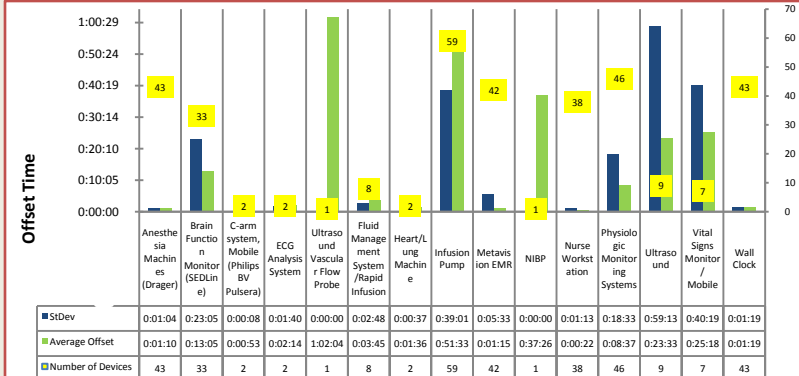


Figure 3 - Overall depiction of medical device clock offsets, including device offsets less than 1 minute. The average offset and standard deviations (in H:MM:SS format) of the device clocks as compared to NIST time are shown in green and blue bars, respectively, and the corresponding number of devices are given in yellow at the end of each bar. Groups are separated by device type.

Data was initially collected on medical devices, information systems and wall clocks. All data was collected from 40 of the Operating Rooms (OR), the Anesthesia Workroom, the Equipment Room, and hallways of the ORs at Massachusetts General Hospital. There were a total of 299 medical devices and 38 Nurse Workstations. The NIST Time was taken as the Standard Time for all measurements and calculations. The average overall time that the systems (including workstations) deviated from the standard NIST clock time was **15 minutes and 24 seconds**. With a maximum deviation of **10 hours 20 minutes and 32 seconds**. **Around 97.63% (329 out of 337) of devices were set at the incorrect time, with 11.28% (84 out of 337) devices having offsets more than 1 hour, and only 2.37% (8 out of 337) were set at the correct time.** For Physiological Monitors, Anesthesia machines, and other equipment that did not display seconds on the machines, it was assumed that seconds = 00. For this reason, a filter of 1 min was used to ignore data from these kinds of devices. Once the filter was applied the average offset time was **27 minutes and 28 seconds**. **Using a 1-minute threshold, around 53.12% (179 out of 337) of the devices had offsets more than 1 minute.** Figure 3 shows all clock offsets per device category collected at Massachusetts General Hospital.

Conclusion

This pilot study supports anecdotal data and first principles that erroneous clock times are pervasive. Given the absence of automatic clock setting capabilities in most medical devices, and typical clock drift, these findings are not surprising. It is likely to take several years for device manufacturers to implement automatic clock-setting capability. Another solution is to implement time-correction in middleware or the EMR, but manufacturers are concerned about legal and regulatory issues with altering medical device data. Networking medical device clocks would not only improve medical record accuracy, but also reduce technician time spent setting and resetting clocks during power outages and (twice yearly) for daylight savings time.

X-Ray Ventilator Synchronization using an Integrated Clinical Environment

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Background:

Patients in the Intensive Care Unit frequently require mechanical pulmonary ventilation. These patients typically have daily portable Chest X-Rays (CXRs) to assess changes in pulmonary infiltrates or acute lung injury, guide clinical decisions regarding antibiotic and diuretic therapy, or assess the position of the tracheal, orogastric, or nasogastric tubes (1-4). The bedside CXR remains the most frequent radiologic examination conducted in critically ill patients. Unfortunately, there is very little data that establishes a correlation between changes in the bedside CXR and a change in the patient's clinical condition. This correlation is limited by several technical (non-physiologic) factors that influence the appearance of the CXR. Among these, the phase of lung inflation at the time of exposure of the CXR plays a prominent role.

For the X-ray images to have optimal diagnostic value, factors such as the focal distance from the X-ray machine to the patient's chest, amount of energy used, and exposure time affect the quality of the X-ray images. But the most important factor affecting film quality is the degree of lung inflation at the instant the film is exposed (5). Since the ventilator runs continuously, the X-ray technician uses visual cues to attempt to manually trigger the X-ray at full lung inflation. The degree of inflation and the pressure in the lung at the instant the CXR is taken is entirely dependent on when the radiographer triggers the machine to acquire the CXR. Manually exposing the radiograph film at the exact peak of inflation may be quite difficult because the inspiratory period may be brief, especially in seriously ill patients who require complex ventilatory modes, or in pediatric patients who typically receive rapid respiratory rates and small tidal volumes. Therefore, this manual attempt at synchronizing X-ray exposure with the ventilatory cycle is frequently ineffective, resulting in CXRs obtained at sub-maximal inflation that do not provide optimal diagnostic information (Figure 1). These may be misinterpreted as demonstrating increased lung water due to crowding of vasculature (6). Chest radiographs of variable quality may lead to additional film acquisitions. Patients are then subjected to concomitant radiation when images are repeated because of poor image quality. For these reasons, tightly controlling the timing of the radiograph during the breathing cycle is beneficial.

Previous studies have shown X-ray/ventilator synchronization leads to significant improvements in image quality and consistency, but these systems have been one-off custom solutions built for research, and therefore have not been commercially available.

The purpose of this project is to prototype an application that utilizes standards based communication methods and a "safety system architecture" to synchronize the acquisition of x-ray images with the desired phase of ventilation to acquire consistent lung images and improve the safety and efficacy of the chest x-ray. A follow-on clinical study is planned. This will be done with a standards-based approach using the functional architecture of the ASTM F2761-09 standard for the Integrated Clinical Environment (ICE). The functional architecture is shown in Figure 2.

An ICE is an environment where monitoring, treatment or diagnosis is performed on a single patient with interconnected medical devices and other equipment. The purpose of integrating medical devices and IT systems into an ICE is to use the newly created system of devices to provide improved safety and effectiveness. The environment contains components enumerated in the ICE standard (the ICE Supervisor, ICE Network Controller, connected ICE-compatible equipment supporting the patient or the procedure), and interface with hospital/patient databases. An ICE is patient-centric. As a patient moves among different venues (e.g., operating room, ICU, emergency department, transport, home), the ICE moves with the patient; however some of the elements of the ICE (operators, medical devices, and even the ICE Network Controller or ICE Supervisor) can change (7).

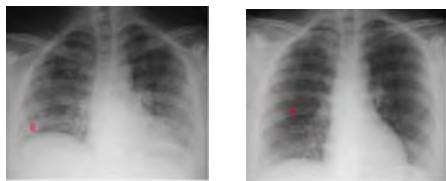


Figure 1: Left - Chest Radiograph at Sub-maximal Inspiration and Right - Chest at Full Inspiration. These CXRs belong to the same patient and were taken at the same time of day on two consecutive days. The CXR on the left, at sub-maximal inflation, loses valuable diagnostic information.

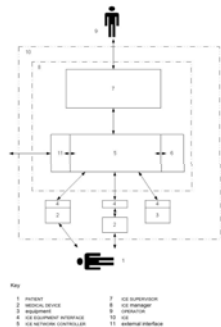


Figure 2 - Architecture of the Integrated Clinical Environment (ICE)

Methodology

Requirements for the system were gathered by meeting with clinicians and technical domain experts to document the current CXR workflow and procedure. A new workflow using an ICE system to synchronize X-ray exposure with ventilation was presented to these experts, and requirements were determined for what is needed to safely perform the synchronization in order to acquire an image at full lung inflation. The proposed system utilizes the analysis of the clinical processes and workflows. A system-level risk analysis was completed, and the mitigation of these risks addresses the "nonfunctional systems requirements". The clinical study plan dictates that the ventilator modes of Assist Control (AC) and Synchronized Intermittent Mandatory Ventilation (SIMV) will be the only modes used, and therefore algorithms for these modes were developed.

System Design:

Design requirements state that an acceptable X-ray capture window is one in which the X-ray is triggered between 90% and 100% of the full inspiration pressure. (Alternatively, tidal volume could be used.) The system must also determine if there is enough time within the 90-100% window to deliver the necessary X-ray exposure.



Figure 3 - Illustrating the X-ray capture window using an SIMV waveform. An acceptable trigger signal would need to be generated between t1 and t2.



Figure 5 - The workflow for the X-ray / ventilator synchronization process. The red boxes highlight where additional hazards may be introduced by making the devices interoperable.

The system designed for the clinical environment utilizes the ICE functional architecture (Figure 2) and application, which synchronizes the X-Ray trigger with the respiratory waveform.

System "Actors" and Roles



The X-ray technician is the user of the system. Prior to using the X-ray Ventilator

Synchronization Application, the X-ray technician is required to configure the X-ray machine and the ventilator. Once the X-ray machine and ventilator have been configured to be used with the Synchronization Application, the technician can initiate the application with the help of the user interface.



The X-ray Ventilator Synchronization Application acquires volume and pressure data from the ventilator using serial communications and then processes that data to determine when the lungs are at "full inspiration". Once the time window of full inspiration is determined, the application triggers the X-ray machine to take an image at full inspiration.



The user interface of the application allows the X-ray technician to document information about the patient, perform BMI, exposure and dose calculations and document parameters for X-ray image capture. It also gives the user the capability to abort image acquisition at any time during the process.

The ventilator is responsible for moving breathable air in and out of a patient who is not able to adequately breathe on their own. There are several modes of ventilation, and our application tackles automating X-ray triggering for the Assist Control (AC) and Synchronized Intermittent Mandatory Ventilation (SIMV) modes. We are working with two ventilators currently, the Puritan Bennett 840 and the Draeger EvitaXL.



The dead-man switch is both the X-ray initiator and the safety mechanism used to prevent people other than the patient from accidentally getting exposed to radiation. The X-ray technician presses the switch to give the algorithm permission to trigger the X-ray machine. If the X-ray technician lets go of the switch, the algorithm will no longer be allowed to trigger the X-ray machine.



This application is intended for patients who have their breathing assisted by mechanical ventilation and who also require some form of chest X-ray imaging. The application is dynamic in order to work with patients on multiple ventilation modes. The application will trigger on assisted breaths or spontaneous breaths, given that the pressure and volume thresholds have been obtained. These thresholds must be reached to have sufficient lung inflation. Also, patients undergoing surgery while on ventilation may be subjected to X-ray imaging to better view the surgical area.



The X-ray Machine is triggered by the application to acquire an image at full inspiration. The application allows the user to document X-ray capture parameters and perform BMI, exposure and dose calculations associated with radiography. At any point during the image acquisition process, the X-ray technician can abort the application, stopping the X-ray machine from exposing the patient to X-ray radiation.

Hazards Analysis:

One of the key aspects of the systems design is performing a systems-level hazard analysis, which will allow for non-functional requirements to be designed into the systems. This will also support validation and verification of the individual devices as well as the system as a whole. One challenge in developing interoperable medical device systems is mitigating new hazards brought on by the combination of multiple devices. Risks associated with stand-alone ventilators and X-ray machines have been documented and given proper mitigation strategies, as this is a requirement for regulatory approval. However, no adequate analysis has been provided for combining the two devices. To properly understand the risks associated with a heterogeneous system of medical devices, detailing the risks and error codes associated with each device was the first step.

Our interoperable system relies on consistent communication with the ventilator. While focusing on the communication of real-time respiratory data (pressure, volume, volumetric flow, etc.), it was also important to communicate any alarms from the devices. In our research we were interested in finding which device alarms could be translated across the device's serial communication port. The algorithm was then adapted to analyze any incoming error message and decide if it is safe to run the synchronization or else abort the application.

In addition to discovering the hazards associated with the ventilator, hazards related to X-ray machines and imaging were also studied. Excess radiation exposure was the main hazard that we attempted to mitigate. Patients, caregivers, and technicians are all susceptible to radiation exposure. To avoid unintentional X-ray exposures, current X-ray machines require the technician to press a dead-man switch continuously through the image acquisition process.

The technician is given the final control over X-ray exposure. The technician has the ability to abort the image anytime during the process by releasing the dead-man switch. We maintained this level of control by including a dead-man button on the application's user interface. The button must be held down throughout the entire imaging process. This ensures that an image is only taken when the X-ray technician deems the process safe. If a person walks into the room unexpectedly, or if the X-ray technician determines that the process is unsafe for any other reason, they can simply release the button and no X-ray is taken. Other risks, such as power loss, unresponsive exposure dials, and cathode disconnected, are present in X-ray machines, but excess exposure is the main hazard affecting patient safety.

There are three main areas where our interoperable system could introduce additional risks. They occur between the ventilator communications, the algorithm triggering the switch, and taking the X-ray image. For example, the ventilator communications could potentially cause the synchronization application to enter a holding state, not allowing any image to be triggered.

The interoperable system communicates with the ventilator but not directly with the X-ray machine. An X-ray image is enabled by controlling the same mechanical switch that is currently used to take an image, thereby requiring no X-ray machine modifications. The schematic in Figure 2 shows our proposed design and highlights potential areas for hazards.

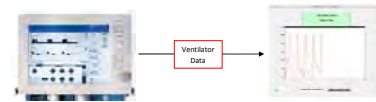


Figure 6 - One pathway where hazards could arise. The red box is the error-prone transition through the workflow. Respiratory data is being streamed from the ventilator to the application to trigger the X-ray image.

Clinical Testing

Clinical testing will take place in the Medical Intensive Care Unit (MICU) at VA Boston. We will test AC and SIMV ventilatory mode. We will evaluate efficacy by comparing the quality of synchronized vs. non-synchronized full-inflation films obtained on the same patient on two consecutive days. IRB approval will be obtained prior to human testing.

Quality of films will be assessed by board-certified radiologists using a point system based on variables particular to chest films, including number of ribs and diaphragmatic curvature to estimate chest inflation, density of lung markings, and clarity of the mediastinum. Other parameters recorded will include beam energy, distance from the X-ray machine to the patient, lung volume and peak pressure at the time of film exposure, as well as a measure of patient size (BMI). Regression analysis will be performed on the collected data using quality as the dependent variable and the parameters above as independent variables. Further, we will record the clinical decisions that were made based on synchronized versus unsynchronized films. We will then generate standards for interoperability interfaces that can be used for portable X-ray machines and ventilators that are generally available and that can be implemented by manufacturers of these devices in the future.

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